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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/577,118

04/26/2006

Arthur W. Crossman

101-04

4316

7590

10/13/2010

Robert J Decker  
2679 Teakwood Drive  
Charlottesville, VA 22911

EXAMINER

MENDEZ, MANUEL A

ART UNIT

PAPER NUMBER

3763

MAIL DATE

DELIVERY MODE

10/13/2010

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/577,118	<b>Applicant(s)</b> CROSSMAN, ARTHUR W.	
	<b>Examiner</b> Manuel A. Mendez	<b>Art Unit</b> 3763	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 26 July 2010.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-49 and 58-68 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-49 and 58-68 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

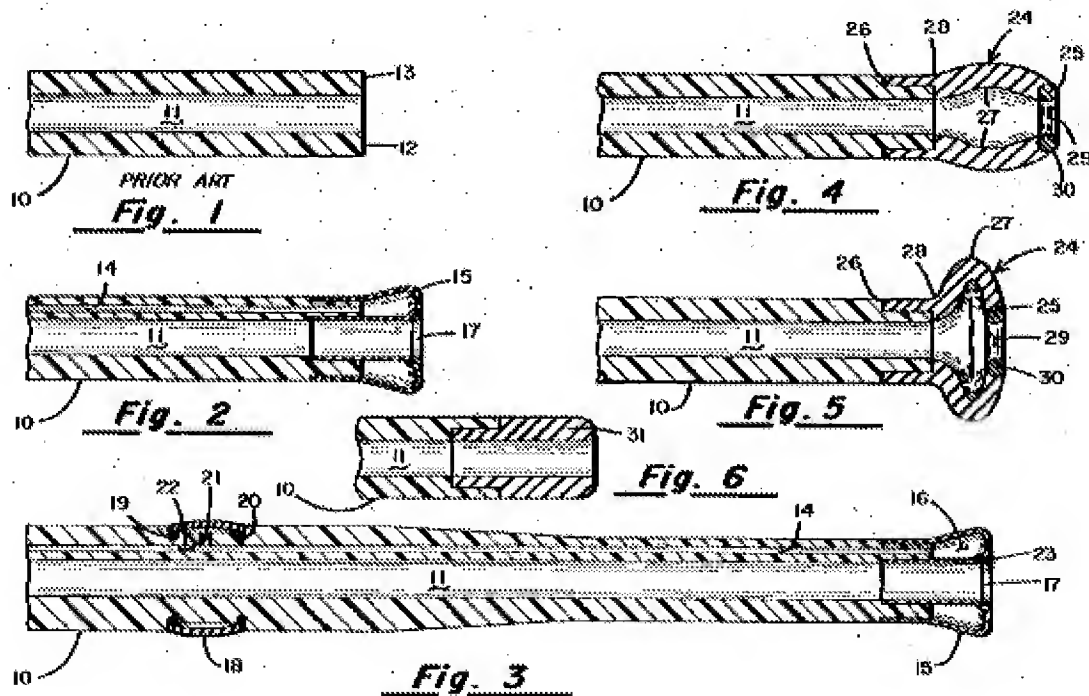
### DETAILED ACTION

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

**Claims 1, 3, and 4 are rejected under 35 U.S.C. 102(b) as being anticipated by Van Tassel et al. (US 4,531,943; hereafter Van Tassel).**



The Van Tassel patent shows in the figures above, a catheter shaft having a proximal portion and a distal portion, and a distal tip disposed on the distal portion, the distal tip having a blunt shape. In relation to claim 3, distal tip (13) is inflatable. In relation to claim 4, figure 4 shows an olive shape distal tip.

***Claim Rejections - 35 USC § 103***

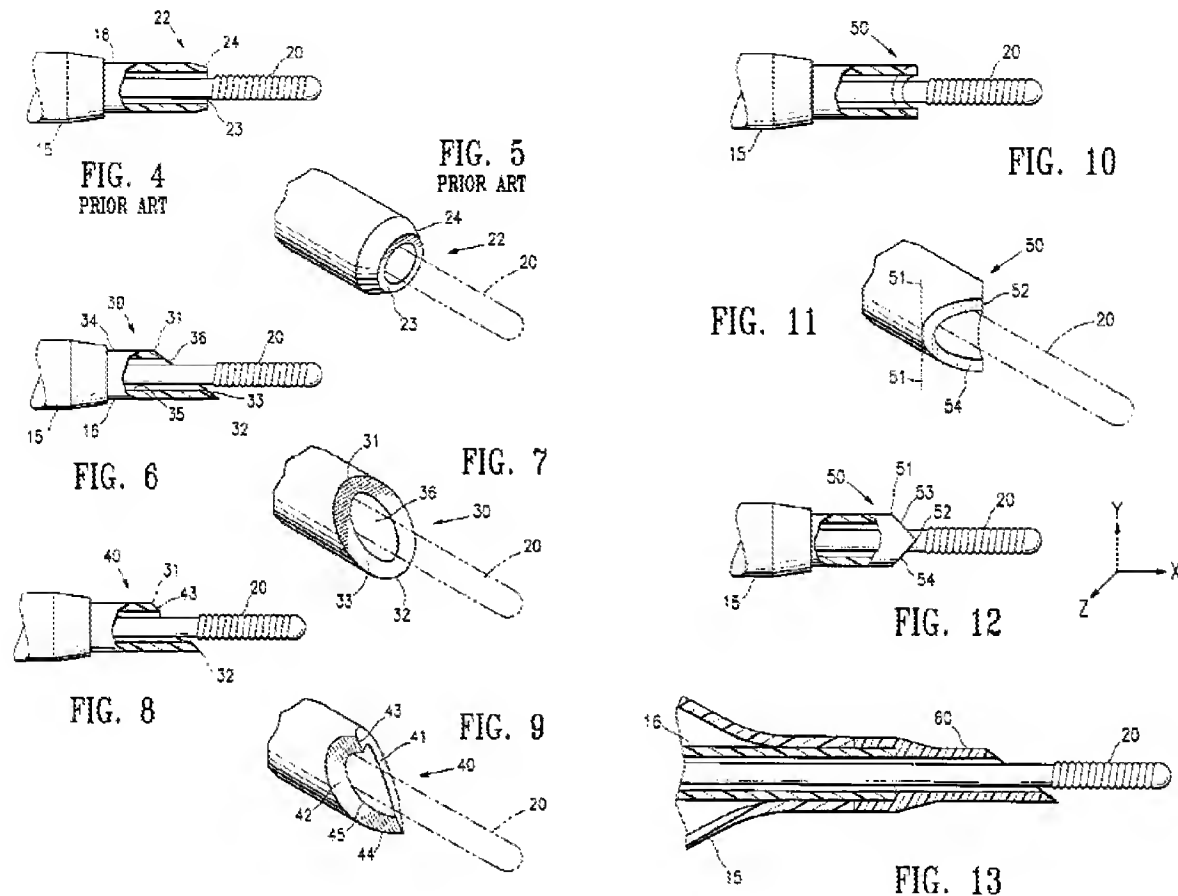
The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Van Tassel et al. (US 4,531,943; hereafter Van Tassel) in view of Makower et al. (US 5,290,310; hereafter Makower).**

The Van Tassel patent does not disclose a sheath to introduce the catheter. However, the use of a sheath to introduce a catheter would have been considered conventional in the art as evidenced by the teachings of Makower. The Makower patent shows in figure 1, a sheath (40) use for the introduction of a catheter into the body. Based on the teachings of Makower, for a person of ordinary skill in the art, modifying the apparatus disclosed by Van Tassel with an introducer, as taught by Makower, would have been considered obvious in the art in view of the proven conventionality of catheter introducer/sheath, and moreover, because catheter sheath use to introduce catheters facilitate the deployment and removal of medical instruments during medical procedures.

**Claims 5-21** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Van Tassel et al.** (US 4,531,943; hereafter Van Tassel) in view of **Lee** (US 6,206,852).



As stated in the previous Section 102 rejection, Van Tassel discloses a set-back extension having an olive shape (claim 14). In the figures above, the Lee patent shows a set-back extension (claim 5), blunt shapes to avoid trauma (claim 6), a tapered set-back extension (claim 7), a set-back extension having a semi-elliptical shape (claims 8, 15, 19, 20), a tip that can be manipulated and that is blunt to avoid trauma (claims 9, 16, 17, 18), a balloon that is inflatable with a pre-formed shape (claims 10, 11, 21), an

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extension located on the distal end of the distal tip (claim 12), and blunt shapes to mitigate trauma (claim 13).

Based on the above observations, for a person of ordinary skill in the art, modifying the Van Tassel catheter with the enhancements discussed above, would have been considered obvious in the art in view of the proven conventionality of these enhancements, and moreover, because the implementation of these enhancements in the catheter disclosed by Van Tassel would have reduce trauma in patients during surgical procedures.

**Claims 22-28** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Van Tassel et al.** (US 4,531,943; hereafter Van Tassel) in view of **Lee** (US 6,206,852), and in further view of **Todd** (US 3983879), **Valley et al.** (US 5,814,016), or **Menasche** (US 4,927,412).

In figure 3, the Van Tassel patent discloses a rounded balloon (18); the Todd patent discloses a ring-like and rounded balloon (30); the Valley patent shows in figures 8A-8C, balloons having preformed shapes for inflation; Van Tassel shows in figure 3, a set-back extension located on the distal end of the distal tip located distally from the balloon (18), the set-back extension has a blunt-shape, the distal tip has, *inter alia*, a rounded shape that is non-traumatic.

Based on the above observations, for a person of ordinary skill in the art, modifying the Van Tassel patent with balloons of different shapes, as taught by Todd, Valley, and Menasche, would have been considered obvious in view of the proven conventionality of these particular balloon shapes, and moreover, because said balloon

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shapes would have been considered obvious alternatives in the design process of the catheter at the time the invention was made.

**Claims 29-40** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Van Tassel et al.** (US 4,531,943; hereafter Van Tassel) in view of **Lee** (US 6,206,852), and in further view of **Todd** (US 3,983,879), **Valley et al.** (US 5,814,016), or **Menasche** (US 4,927,412), and in further view of **Yoon** (US 5,613,950).

Van Tassel does disclose an embodiment having multiple balloons, a proximal balloon (18) and a set-back extension having a blunt distal tip that is inflatable (figure 3). Van Tassel also discloses a distal end having a conical shape (non-traumatic). Additionally, the Yoon patent is presented in this rejection to demonstrate the conventionality of using multiple balloons in one catheter, and moreover, the use of balloons of different shapes. (See figure 11A). Accordingly, modifying the Van Tassel patent with multiple balloons would have been considered an obvious design choice.

In relation to claims 34-40, based on cited evidence, all the structural elements of the catheter and set-back extension would have been known at the time the invention was made. In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, “where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device”. Accordingly, absent any criticality,

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variations in size and/or dimensions would have been considered obvious choices in the process of designing the catheter.

**Claims 41-49** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Van Tassel et al. (US 4,531,943; hereafter Van Tassel)** in view of **Lee (US 6,206,852)**, and in further view of **Todd (US 3,983,879)**, **Valley et al. (US 5,814,016)**, **Menasche (US 4,927,412)**, or **Yoon (US 5,613,950)**, and in further view of **Duane et al. (US 6,800,065; hereafter Duane)** or **Shturman (US 4,770,653)**.

Van Tassel is silent about the intended uses recited in the cited claims. However, the Duane patent demonstrates the conventionality of using introducing catheters in to the heart via veins or arteries, and conducting angioplasty, PTA, and PTCA procedures. The Shturman patent demonstrates the conventionality of using catheters to perform laser angioplasty.

Based on the above observations, for a person of ordinary skill in the art, modifying the Van Tassel patent to perform the procedures disclosed above, as taught by Duane and Shturman, would have been considered obvious in view of the conventionality of these procedures, and moreover, because such modifications would have enhanced the efficiency of the catheter in question.

**Claim 58 is** rejected under 35 U.S.C. 102(b) as being anticipated by **Van Tassel et al. (US 4,531,943; hereafter Van Tassel)** in view of **Horn et al. (US 5,087,247; hereafter Horn)**.



The Van Tassel patent does not disclose apertures disposed on the sidewall of the catheter. However, the use of apertures in catheter designs would have been considered conventional in the art as evidenced by the teachings of Horn.

The Hoorn patent shows in figure 2, a catheter having multiple apertures along the sidewall of the catheter. Accordingly, for a person of ordinary skill in the art, modifying the catheter disclosed by Van Tassel, with sidewall apertures, as taught by Horn, would have been considered obvious in view of the proven conventionality of this particular enhancement, and moreover, because such apertures would have provided the capability of infusing fluids along the wall of the catheter.

**Claims 59-61** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Van Tassel** et al. (US 4,531,943; hereafter Van Tassel) in view of **Lee** (US 6,206,852), and in further view of **Horn** et al. (US 5087247; hereafter Horn) or **Abiuso** et al. (US 5213576; hereafter Abiuso).

The Van Tassel patent does not disclose apertures disposed on the sidewall of the catheter or in the sidewall of the balloon. However, the use of apertures in catheter designs located along the sidewall and/or in the wall of the balloon would have been considered conventional in the art as evidenced by the teachings of Horn and Abiuso.

The Hoorn patent shows in figure 2, a catheter having multiple apertures along the sidewall of the catheter. Abiuso shows in figure 4, an embodiment having a balloon with apertures in fluid communication with the catheter lumen.

Based on the above evidence, for a person of ordinary skill in the art, modifying the catheter disclosed by Van Tassel, with catheter sidewall and balloon sidewall

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apertures, as taught by Horn and Abiuso, would have been considered obvious in view of the proven conventionality of this particular enhancement, and moreover, because such apertures would have provided the capability of infusing fluids along the wall of the catheter and the balloon, and therefore extending the capability of infusing fluid into a large area within the body.

**Claim 62** is rejected under 35 U.S.C. 103(a) as being unpatentable over **Van Tassel et al.** (US 4,531,943; hereafter Van Tassel) in view of **Lee** (US 6,206,852), and in further view of **Todd** (US 3,983,879), **Valley et al.** (US 5,814,016), or **Menasche** (US 4,927,412), and in further view of **Yoon** (US 5,613,950), and in further view of **Horn et al.** (US 5,087,247; hereafter Horn) or **Abiuso et al.** (US 5,213,576; hereafter Abiuso).

The Van Tassel patent does not disclose apertures disposed on the sidewall of the catheter or in the sidewall of the balloon. However, the use of apertures in catheter designs located along the sidewall and/or in the wall of the balloon would have been considered conventional in the art as evidenced by the teachings of Horn and Abiuso.

The Horn patent shows in figure 2, a catheter having multiple apertures along the sidewall of the catheter. Abiuso shows in figure 4, an embodiment having a balloon with apertures in fluid communication with the catheter lumen.

Based on the above evidence, for a person of ordinary skill in the art, modifying the catheter disclosed by Van Tassel, with catheter sidewall and balloon sidewall apertures, as taught by Horn and Abiuso, would have been considered obvious in view of the proven conventionality of this particular enhancement, and moreover, because such apertures would have provided the capability of infusing fluids along the wall of the

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catheter and the balloon, and therefore extending the capability of infusing fluid into a large area within the body.

**Claims 63-68** are rejected under 35 U.S.C. 103(a) as being unpatentable over **Van Tassel** et al. (US 4,531,943; hereafter Van Tassel) in view of **Lee** (US 6,206,852), and in further view of **Todd** (US 3983879), **Valley et al.** (US 5,814,016), **Menasche** (US 4,927,412), or **Yoon** (US 5,613,950), and in further view of **Duane** et al. (US 6,800,065; hereafter Duane) or **Shturman** (US 4,770,653), and in further view of **Horn** et al. (US 5087247; hereafter Horn) or **Abiuso** et al. (US 5213576; hereafter Abiuso).

The Van Tassel patent does not disclose apertures disposed on the sidewall of the catheter or in the sidewall of the balloon. However, the use of apertures in catheter designs located along the sidewall and/or in the wall of the balloon would have been considered conventional in the art as evidenced by the teachings of Horn and Abiuso.

The Hoorn patent shows in figure 2, a catheter having multiple apertures along the sidewall of the catheter. Abiuso shows in figure 4, an embodiment having a balloon with apertures in fluid communication with the catheter lumen.

Based on the above evidence, for a person of ordinary skill in the art, modifying the catheter disclosed by Van Tassel, with catheter sidewall and balloon sidewall apertures, as taught by Horn and Abiuso, would have been considered obvious in view of the proven conventionality of this particular enhancement, and moreover, because such apertures would have provided the capability of infusing fluids along the wall of the

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catheter and the balloon, and therefore extending the capability of infusing fluid into a large area within the body.

***Examiner's Comment***

In response to applicant's arguments in the amendment dated 07/26/2010, the examiner of record has corrected the pending claims to claims 1-49 and 58-68.

Accordingly, this new office action is not a final office action.

In relation to the Correction of Official Filing Receipt, the examiner will consult with the head clerk of Group 3700 in order to seek a solution to this problem with the Claim of Priority. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Manuel A. Mendez whose telephone number is 571-272-4962. The examiner can normally be reached on 0730-1800 hrs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Nicholas D. Lucchesi can be reached on 571-272-4977. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Manuel A. Mendez/

Primary Examiner, Art Unit 3763

Manuel A. Mendez  
Primary Examiner  
Art Unit 3763

MM